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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,715	06/19/2001	Malcolm Richard Boyd	4-31830B	3629

1095 7590 04/09/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PENG, BO	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/884,715	BOYD, MALCOLM RICHARD	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/26/06&10/2/06.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 7,9,10,19,20,23,25,26 and 46- 48 is/are ~~allowed.~~ allowable, but see Interference section of action

6)☐ Claim(s) 8,11-18,21,22,24 and 27-45 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

2. This Office Action is in response to the amendment filed October 2, 2006, and Applicant's remarks filed on February 23, 2006. Claims 23-48 are newly added. Claims 7-48 are pending and are considered in this Office action.

35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of Claims 8, 11-18, 21, 22 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement **is maintained**, now extended to new Claims 24 and 27-45, for the reasons of record.

5. Applicant submits Webster's Dictionary providing a definition of prophylaxis as a protected treatment for or prevention of disease. Then Applicant argues that the prophylactic measures using the compounds of the invention are not limited to prevention of infection but are also to prevent development of infection or where the infection has already developed, to protect against worsening of the process (Remarks, Paragraph 2, p. 9). Applicant also argues that the

specification provides sufficient guidance for a skilled artisan to practice the method because famciclovir and penciclovir are well known in the art and practice Applicant's prophylaxis method requires only routine experimentation (Remarks, Paragraphs 4 and 5, p. 8).

6. Applicant's argument is considered but found not persuasive. Unlike Webster's definition of prophylaxis as a protected treatment for or prevention of disease, the instant claims are directed to a method of prophylaxis of HSV infection (Emphases added). As indicated in the previous Office action, famciclovir and penciclovir are capable of preventing HSV-induced disease, but are not capable of preventing HSV infection. The prior art teaches that famciclovir inhibits but does not prevent HSV infection in an animal model for viral latency (See Thackray et al). The specification provides a working example, in an animal model, for treatment of a pre-existing infection. There is no working example demonstrating prevention of HSV infection. Thus, based on the Webster's definition of prophylaxis, considering the state of the art, the limited teachings in the specification, and the absence of a working example, it is concluded that undue experimentation would be required to practice "prophylaxis of herpes simplex virus infection" as claimed.

35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The rejection of Claims 8, 11, 12, 16-18 and 21 under 35 U.S.C. 102(b) as being anticipated by Boker et al, **is maintained**.

9. Applicant argues that Boker teaches treatment of HBV, but the instant invention is directed to a pharmaceutical composition for treating HSV.

10. In response, Claims 8 and 16 reads on a method of treatment or prophylaxis of herpes simplex virus infections in a human in need thereof, which method comprises administering to said human, orally or parenterally, an effective amount of a nucleoside analogue active against herpes simplex virus selected from the group consisting of penciclovir and famciclovir, or a pharmaceutically acceptable salt or ester thereof and an effective amount of a pharmaceutically acceptable immunosuppressant (Emphasis added).

11. To prevent HSV infections in a human in need, the patient population can be anyone in need, including HBV infected patients. Since immunosuppressed patients are at risk for newly-transmitted infections or reactivation of latent infections, they meet the requirement for a human in need of prophylaxis of a herpes simplex virus infection. Boker teaches a method of prophylaxis of re-infection of HBV in liver transplantation patient with an immunosupresant and, at the same time, with oral famciclovir. The method steps taught by Boker meet the limitations of instant method of prophylaxis of herpes simplex virus infections in a human in need. Thus, the method of prophylactic treatment taught in the reference inherently constitutes prophylaxis against herpesvirus infection, even though the reference is silent upon the topic of herpesviruses. Therefore, the rejection of Claims 8, 11, 12, 16-18, 21 under 35 U.S.C. 102(b) as being anticipated by Boker et al, is maintained.

Interference

12. Applicant provides some arguments regarding interference issue. The examiner has placed Applicant's arguments in record. Interference issue will be addressed when all claims in allowable condition.

Allowable Subject Matter

13. Apart from interference issues with US 6337324, Claims 7, 9, 10, 19, 20 23, 25, 26 and 46-48 are allowable, as the available prior art does not teach or suggest combining an immunosuppressant in the same composition with famciclovir or penciclovir.

14. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bo Peng, Ph.D.
April 2, 2007.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600